John M. Farrell (CA Bar No. #99649)
farrell@fr.com
FISH & RICHARDSON P.C.
500 Arguello Street, Suite 500
Redwood City, CA 94063
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

Jonathan E. Singer (CA Bar No. #187908)
singer@fr.com
FISH & RICHARDSON P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Juanita R. Brooks (CA Bar No. #75934)
brooks@fr.com
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Attorneys for Plaintiff
GILEAD SCIENCES, INC.

Additional counsel listed on signature page

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN JOSE DIVISION)

GILEAD SCIENCES, INC., Plaintiff and Counterdefendant, v. MERCK & CO, INC. (Defendant only), MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC., Defendants and Counterclaimants.	Case No. 5:13-cv-04057-BLF/PSG **GILEAD SCIENCES, INC.'S BENCH TRIAL BRIEF ON EQUITABLE DEFENSES**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

I. INTRODUCTION

What Merck did was wrong. Merck sent its HCV patent prosecutor to a special meeting with Pharmasset where the structure of Pharmasset's lead nucleoside compound, PSI-6130, was to be disclosed. The disclosure of the structure of PSI-6130 was a big deal. This would be the first time the structure would be disclosed to anyone outside of Pharmasset. And Merck understood that Pharmasset was only willing to provide the structure of PSI-6130 to a limited number of people from Merck who were ***firewalled***. In other words, the structure was to be given only to certain people who had ***no involvement*** with Merck's internal HCV program.

Merck, unfortunately, did not play by these rules. Rather than comply with the parties' agreement that only firewalled individuals could learn the structure, Merck instead sent its patent prosecutor—Philippe Durette—to obtain the structure. And while obtaining the structure, Dr. Durette told Pharmasset something that simply was not true: that he was within the firewall. Dr. Durette, it turns out, was not under the firewall, but rather was intimately involved with the Merck-Isis collaboration. In fact, Dr. Durette was the person at Merck responsible for drafting patent claims that could block Merck's competition from selling therapies for HCV.

And not only did Dr. Durette learn the structure at this meeting, but he also learned that Pharmasset's patent application describing PSI-6130 would soon publish. So Dr. Durette waited. He waited until Pharmasset's application published, and then Dr. Durette ran to the patent office, cancelled all pending claims, and wrote new claims to target PSI-6130 with the hopes of giving Merck the right to exclude Pharmasset from selling PSI-6130 and related compounds.

Merck's predatory patent strategy is reprehensible. This Court should not allow Merck to benefit from its scheme, and Merck should be precluded from asserting its patents against Gilead's sofosbuvir for unclean hands. In addition, the Court should find that Merck has waived its claims, as explained below.[1]

[1] Gilead will not be going forward on its defenses of equitable estoppel, laches, or indefiniteness at the March 29 bench trial.

II. FACTUAL BACKGROUND

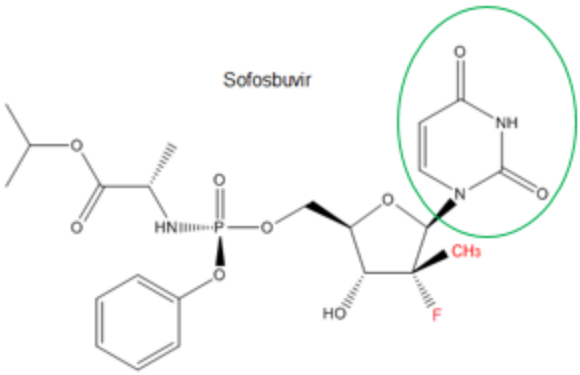
A. GILEAD AND ITS DECLARATORY JUDGMENT ACTION

In this action, Plaintiff Gilead Sciences, Inc. seeks an order declaring that the asserted claims of Defendants' U.S. Patent Nos. 7,105,499 (the "'499 patent") and 8,481,712 (the "'712 patent") are unenforceable against Gilead stemming from the sale and use of its accused products, the groundbreaking HCV treatments Sovaldi® and Harvoni®.

A jury trial was held from March 7-22 to determine the validity of asserted claims 1-2 of the '499 patent, and asserted claims 1-3, 5, 7, and 9-11 of the '712 patent. There remain two equitable defenses that require the Court's adjudication. First, Gilead contends that Merck's dishonesty and misuse of Pharmasset's information in obtaining its patents prevents Merck from asserting those patents against Gilead, under the doctrine of unclean hands. Second, Gilead contends that Merck's course of conduct and dealings with Pharmasset in attempting to acquire the compounds it now considers infringing prevents Merck from asserting its patents against Gilead, under the doctrine of waiver.

Gilead is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines for life-threatening diseases. In 2013, Gilead received FDA approval for Sovaldi®, a treatment for hepatitis C virus (HCV) containing the active ingredient sofosbuvir. Gilead has also commercialized sofosbuvir since 2014 under the trade name Harvoni® in a fixed-dose combination with its internally-developed HCV drug, ledipasvir. These two products set a new standard of care for treating HCV infection and have cured thousands of patients to date.

Sofosbuvir is a nucleotide prodrug that treats HCV by directly interfering with the HCV life cycle. The chemical structure of sofosbuvir includes a 2' methyl (a C_1 alkyl) up, and a 2' fluorine (F) down group, marked in red, and a single ring, uridine base, marked in green:



Sofosbuvir was invented at a small nucleoside research company, Pharmasset, which Gilead acquired in 2011. Pharmasset's Michael Sofia, along with Jinfa Du and Peiyuan Wang, invented sofosbuvir. Pharmasset's Jeremy Clark also invented a compound in 2003, known as PSI-6130, that also has a 2' methyl up, 2' F down configuration. PSI-6130 was an important predecessor compound to sofosbuvir at Pharmasset. Drs. Sofia, Du, and Wang, as well as Mr. Clark, have been awarded patents for their respective work.

Merck first learned that the 2' methyl up, 2' F down configuration held promise for treating HCV infection through confidential discussions with Pharmasset in 2004. As stipulated at trial, neither Merck nor its partner Isis ever tested a 2' methyl up, 2' F down nucleoside before filing the application for the patents at issue in this case.

B. MERCK'S PREDATORY PATENTING SCHEME

Merck learned of the 2' methyl up, 2' F down structure of PSI-6130 in 2004 under a confidentiality agreement between Pharmasset and Merck. Rather than abide by strict requirements Pharmasset placed on the disclosure of this information, Merck inappropriately had its HCV patent prosecutor, Dr. Durette, obtain the structure of PSI-6130. In so doing, Dr. Durette misrepresented to Pharmasset that he was firewalled from Merck's HCV program. What Dr. Durette ended up doing with the knowledge he learned from Pharmasset—knowledge that he should have never been exposed to—was to draft new patent claims targeting PSI-6130 and related structures.

In 2003-2004, Merck evaluated Pharmasset's HCV program, including PSI-6130, under a confidentiality agreement. Despite this confidentiality agreement, Pharmasset initially was unwilling to provide the structure of PSI-6130 to anyone at Merck. Pharmasset was willing, however, to provide meaningful information about PSI-6130. In particular, Pharmasset told Merck that PSI-6130 was a nucleoside NS5B polymerase inhibitor that was active in both the replicon and NS5B assays. Pharmasset further gave Merck blinded samples of PSI-6130 and allowed Merck to evaluate for itself the biological properties of the compound. Merck evaluated them positively. Accordingly, Merck was well aware that PSI-6130 was an anti-HCV compound with the same mechanism of action and in the same field as both the Merck-Isis collaboration and the patent applications that Dr. Durette was prosecuting.

In light of the promising biological properties associated with PSI-6130, Merck expressed interest in licensing the compound from Pharmasset. As the next step in the process, Pharmasset was willing to provide the structure of PSI-6130 under strict terms to Merck. Namely, Pharmasset would provide the structure to a limited number of people who had not been and would not be part of Merck's internal HCV program. These "firewalled" individuals were obligated not to share structural information about PSI-6130 to anyone involved with Merck's internal HCV program.

Beyond Pharmasset's clear requirements, Merck had its own company policy that, if followed, would prevent a Merck patent prosecutor like Dr. Durette from learning anything about Pharmasset's compounds. In short, Dr. Durette, per both Pharmasset's express conditions and Merck's own policy, should never have received the structure of PSI-6130.

Dr. Durette confirmed this under oath at his deposition. He testified that he would not have been told the structure because he was a patent attorney working on patent applications in the same subject area as Pharmasset's compounds. (Durette Dep. Tr. (EX-2388) at 38:01-13.) Dr. Durette also explained that it was against Merck's company policy to have a Merck patent prosecutor participate in licensing discussions in a related area. (Durette Dep. Tr. (EX-2388) at

38:25-39:07.) Dr. Durette explained the reasons behind this policy at his deposition, testifying that it would have been inappropriate for him to learn the structure of PSI-6130 because it would have "tainted" his judgment as to what claims to pursue in the Merck-Isis collaboration:

> Q: Again, why would it have been inappropriate or wrong for you to have been told the 6130 structure?
>
> A: It would have tainted my judgment as to what claims to pursue in the Merck/Isis collaboration.

(Durette Dep. Tr. (EX-2388) at 38:21-24.)

While Dr. Durette accurately testified that company policy would have prohibited him from receiving the structure, and that receiving the structure would have tainted his judgment as to what claims to pursue in the Merck-Isis collaboration, Dr. Durette also provided testimony that turned out not to be true. Specifically, Dr. Durette clearly and unequivocally ***denied*** learning the structure of PSI-6130:

> Q: How are you so sure 11 years later that you were never told what the structure was for the 6130 compound?
>
> A: The structure was not revealed to me by individuals at Merck or otherwise. ***I'm positive of that***. I never saw a structure of the Pharmasset compounds until it published later on it time.

(Durette Dep. Tr. (EX-2388) at 31:4-10 (emphasis added)).

At the time of his deposition, Dr. Durette was unaware of a key fact: Pharmasset's Alan Roemer had taken contemporaneous notes of the March 17, 2004 phone call that recounted the disclosure of the structure to Dr. Durette. Dr. Durette was unaware that Gilead had contemporaneous proof, and a witness who could testify from first-hand knowledge, that Dr. Durette did indeed receive the structure of PSI-6130.

Faced with this irrefutable evidence that Pharmasset had disclosed the structure to him, Dr. Durette told a completely different story at trial. Unable to say that he never obtained the structure of PSI-6130 in light of this proof, Dr. Durette said that at the time of his deposition he

had simply forgotten that he received the structure but at trial he recalled that he did receive the structure. With this new-found memory, Dr. Durette scrambled to try to justify his receipt of the structure. For example, Dr. Durette testified that, prior to receiving the structure, he had a conversation with his management where it was concluded that there would likely be no overlap between Dr. Durette's prosecuting activities and PSI-6130. Dr. Durette's testimony on this point gave the impression that Merck did not know that PSI-6130 was an NS5B inhibitor. This testimony, however, was also false. Merck had asked, and had been told—prior to the March 17 call—that PSI-6130 was an NS5B inhibitor that was active in the NS5B assay. And Merck had tested it for itself and confirmed it to be true. Dr. Durette's attempt to justify why he attended the meeting to receive the structure lacks credibility and serves to further emphasize that what Merck did here is fundamentally wrong.

Dr. Durette's "no harm no foul" justification falls flat as well. Dr. Durette testified that after learning the structure, he immediately recused himself from further Pharmasset due diligence activities. But that was the wrong remedy. What Dr. Durette should have done, and what Dr. Durette was obligated to do, was to recuse himself ***from prosecuting Merck's HCV patent applications*** because, as he had to admit at his deposition, his judgment was "tainted." He did nothing of the sort. Rather, not only did Dr. Durette continue to prosecute Merck's HCV applications, Dr. Durette wrote new patent claims specifically targeting Pharmasset's technology. Tainted he was.

At trial, Dr. Durette provided yet another excuse as to why he chose in 2005—despite no prompting from the patent office—to rewrite Merck's pending patent claims to focus on 2' methyl up, 2' F down compounds. Dr. Durette testified that he wanted to expedite prosecution and that he rewrote the claims to focus on "subject matter that was ***most important*** to the [Merck-Isis] collaboration." (Trial Tr. 404:14-19 (emphasis added).) This testimony is not credible. As the Court is aware, Merck (and Isis) never made, never tested, and never used a 2' methyl up, 2' F down nucleoside during their collaboration. What Dr. Durette's claim change

actually did was to remove from the pending claims each and every one of the roughly 2,000 nucleoside compounds that Merck and Isis had made or tested as of January 18, 2002. Dr. Durette's new claims drafted in 2005 cover not a single compound made or tested by Merck and Isis during the entire Merck-Isis collaboration. Far from focusing on the most important compounds coming out of the Merck-Isis collaboration, Dr. Durette's claim change focused on Pharmasset's PSI-6130 compound and Pharmasset's work with 2' methyl up, 2' F down nucleosides. And while rewriting these claims, Dr. Durette never informed the patent office that 1) the structure of PSI-6130 had been disclosed to him, or 2) the new claims did not cover any compounds that Merck or Isis actually made or tested. Instead, Dr. Durette blithely stated to the Patent Office that the new claims were "fully supported" by the patent specification.

If Dr. Durette had been candid with the Patent Office regarding the true origin of his new claims, the Patent Office likely would have rejected Dr. Durette's claims. Indeed, a similar scenario played out in a subsequent patent application where Dr. Durette attempted to claim Pharmasset's and Jeremy Clark's work. In September 2005, Dr. Durette filed patent application No. 11/236,224, which encompassed 2' methyl up, 2' F down nucleosides having a double-ring base. The Patent Office rejected these claims for lack of written description support. In attempting to overcome this rejection, Dr. Durette pointed the Patent Office to an article written by Jeremy Clark to suggest the claimed compounds, including nucleoside analogs with a 2'methyl up, 2' F down configuration, were active. Rather than accepting Dr. Durette's argument, the Patent Office found that the Clark article supplied by Dr. Durette supported rejecting the claims because Mr. Clark was not a named inventor on the '224 application. Dr. Durette ultimately abandoned this application. The fate of the '224 application is telling. Had Dr. Durette been candid with the Patent Office while prosecuting what would become the '499 patent, the Patent Office would have been alerted to the fact that Dr. Durette was trying to claim Pharmasset's invention—not Merck's—and would have recognized the dearth of support in the specification for the new claims.

In the years following Jeremy Clark's invention of PSI-6130, Pharmasset continued to invent and develop novel nucleosides for the treatment of HCV. This ultimately culminated in Dr. Sofia's invention of sofosbuvir. And while Pharmasset continued its scientific innovations, Merck continued with its predatory patent scheme. In particular, well after the structure of sofosbuvir had been publicly disclosed, after Pharmasset had unequivocally told Merck it believed the '499 patent was invalid, and after Gilead purchased Pharmasset, thereby signaling to the world that sofosbuvir would be a backbone of future HCV treatments, Merck went back to the Patent Office, in continuation of Dr. Durette's scheme (and using a new patent application that Dr. Durette had filed). Merck's patent prosecutor, this time Mr. Jeffrey Bergman,[2] while knowing the structure of sofosbuvir, rewrote pending patent claims and added new, narrower claims to target the metabolites of sofosbuvir. Despite Merck and Isis scientists never having made or tested a single compound falling within the claims of Merck's '712 patent during the entire Merck-Isis collaboration, Merck's patent attorney more than a decade after the January 18, 2002, filing date, rewrote claims to target sofosbuvir's metabolites. Mr. Bergman's claiming strategy was no coincidence. Indeed, at the same time he was seeking these claims, Merck and Isis were negotiating to renew their collaboration agreement with the express purpose of outlining their rights and responsibilities with respect to, and dividing any potential damages award resulting from, an infringement action against Gilead. And within a month of the '712 patent issuing, Merck and Isis made good on their renewed deal, and approached Gilead to kick-start this litigation.

C. MERCK'S VEILED THREATS OF ASSERTING ITS PATENTS CONSTITUTE WAIVER

While writing patent claims specifically to cover Pharmasset's technology, Merck also engaged Pharmasset in partnering and acquisition talks on numerous occasions between 2003 and 2011. Merck sought to obtain Pharmasset's HCV nucleoside compounds (including PSI-6130 and PSI-7977), through numerous licensing proposals and several attempted acquisitions of

[2] Dr. Durette had retired from Merck by this time.

the company. (EX-0069; Pomerantz Dep. Tr. (EX-2387) at 58:25-59:17; 59:21-60:04). Many of these licensing proposals recognized Pharmasset's 2'methyl, 2'F nucleosides as "proprietary" to Pharmasset. (EX-2390.) These discussions concluded only when Gilead purchased Pharmasset in November 2011. While Merck, on occasion, mentioned patents that Merck had, Merck never demonstrated to Pharmasset that Merck legitimately believed that Merck could or would sue Pharmasset or an acquirer such as Gilead over Merck's patents that might encompass either PSI-6130 or PSI-7977.

III. GILEAD'S DEFENSES

A. MERCK'S INFRINGEMENT CLAIMS ARE BARRED BY UNCLEAN HANDS

In light of Merck's deceitful conduct in obtaining its patents asserted in this case, Merck should be precluded from maintaining its infringement allegations against Gilead. It is well settled that "he who comes into equity must come with clean hands." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). This maxim "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Id.* In order to maintain its infringement allegation, equity "require[s] that [Merck] shall have acted fairly and without fraud or deceit as to the controversy in issue." *See id*. at 814-15. In applying the doctrine, this Court is "not bound by formula or restrained by any limitation." *Id.* at 815. "Accordingly one's misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character. ***Any willful act*** concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim . . . ." *Id.* (emphasis added).

Moreover, in patent cases that concern not only private interests but also the public interest, the doctrine of unclean hands "assumes even wider and more significant proportions." *Id*. at 815. This is because the public has "a paramount interest in seeing that patent monopolies

spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope." *Id*. at 816.

The equitable doctrine of "unclean hands" bars a patentee's recovery against an accused infringer if "some unconscionable act of [the patentee] has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation." *Aristocrat Techs. v. Int'l Game Tech.*, No. C-06-03717 RMW, 2010 WL 2486194, at *2 (N.D. Cal. June 15, 2010) (quoting *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933)); *see also Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 251 (1944) (reversing finding of patent infringement and ordering judgment be set aside due to plaintiff's presentation of false testimony and fabrication of evidence); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 247 (1933) (affirming dismissal of patent infringement case where the patentee had unclean hands due to its presentation of false testimony); *see also Mas v. Coca-Cola Co.*, 163 F.2d 505, 511 (4th Cir. 1947) (finding the plaintiff had unclean hands and upholding dismissal of plaintiff's suit where plaintiff lied to the Patent Office and fabricated evidence) ("No court of equity ought to be required to listen to a man whose very presence suggests danger to the administration of justice and whose past conduct affecting the matter in litigation would cast doubt upon the ability of the court to ascertain from him the truth with respect thereto."). Unlike inequitable conduct, the doctrine of unclean hands does "not present any standard for materiality." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (2011). A party must prove unclean hands by clear and convincing evidence. 4 Annotated Patent Digest § 27:130; *see also Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1374 (Fed. Cir. 2001) (finding clear and convincing evidence that patentee had fabricated lab notebook pages and affirming district court's finding of unclean hands).

Merck's conduct here violates the doctrine of unclean hands. As detailed above, Pharmasset was willing to provide the structure of PSI-6130 ***only to*** firewalled individuals. Merck not only understood this, but also had their own policy that a Merck patent prosecutor

could not participate in licensing discussions in a related field. In spite of this, Merck sent Dr. Durette to obtain the structure of PSI-6130 from Pharmasset. Dr. Durette told Pharmasset that he was within the firewall. This was not true. Dr. Durette was actually prosecuting Merck's HCV patent applications. Dr. Durette proceeded to write new patent claims targeting Pharmasset's technology. And Dr. Durette never informed the Patent Office that he obtained the structure of PSI-6130 prior to rewriting Merck's patent claims. This is bad faith conduct; this is deceitful conduct; this is unclean hands.

Merck's predatory claiming strategy should be rejected. Merck has asserted infringement allegations over the same claims that Dr. Durette drafted. Merck also has asserted infringement allegations over claims drafted by Mr. Bergman that issued from an application that Dr. Durette filed in furtherance of this scheme: claims drafted a decade after the patents in this case were filed, and claims drafted only after Mr. Bergman learned the structure of sofosbuvir. Merck comes to this court with unclean hands, and Merck should be denied access.

B. MERCK'S INFRINGEMENT CLAIMS ARE BARRED BY WAIVER

A patentee impliedly waives its right to enforce a patent against an accused infringer where the patentee's "conduct was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished." *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1348 (Fed. Cir. 2011). The patentee's waiver effectively creates an implied license for the accused infringer to make, use, or sell the patented invention. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 609 F. Supp. 2d 988, 1030 (N.D. Cal. 2009) (citing *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997)). A party must prove waiver by a preponderance of the evidence. *Oracle Am., Inc. v. Google Inc.*, No. C 10-03561 WHA, 2012 WL 1965778, at *2 (N.D. Cal. May 31, 2012).

Merck's conduct evidences an implied waiver. Despite claiming to have invented the class of compounds covering Pharmasset's PSI-6130 and PSI-7977 as of January 2002, Merck subsequently, on numerous occasions over many years, made numerous attempts to license these

compounds, and to acquire Pharmasset outright in order to gain access to these compounds. (Trial Tr. at 343:17-25; 428:20-429:2; EX-2387 at 42:07-22.) Merck also negotiated an agreement with another pharmaceutical company, Roche, to attempt to get access to sofosbuvir. (Trial Tr. at 1526:7-1527:7.) Merck's offers to license or purchase that which it had an exclusive right to (and an exclusive right to exclude Pharmasset from), and its negotiations with Roche, are fundamentally inconsistent with an intent to enforce its patent rights. *See Hynix*, 645 F.3d at 1348. It was reasonable for Pharmasset to believe that Merck, as the patent holder, knew the scope of its claimed invention and had relinquished its enforcement rights. As such, even if not intentionally, Merck impliedly waived the right to assert the '499 patent. The '712 patent alleges priority to the same patent application, contains similar claims obtained to target sofosbuvir, and is equally subject to waiver.

Dated: March 22, 2016

FISH & RICHARDSON P.C.

By: */s/ Gregory R. Booker*
Gregory R. Booker

Attorneys for Plaintiff
GILEAD SCIENCES, INC.

Additional counsel:
Douglas E. McCann (*Pro Hac Vice*)
dmccann@fr.com
Gregory R. Booker (*Pro Hac Vice*)
booker@fr.com
Robert M. Oakes (*Pro Hac Vice*)
oakes@fr.com
Elizabeth Flanagan (*Pro Hac Vice*)
eflanagan@fr.com
Joseph B. Warden (*Pro Hac Vice*)
warden@fr.com
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19801
Telephone: (302) 652-5070
Facsimile: (302) 652-0607